



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,076	03/02/2006	Toshiyuki Takagi	DAISAN126512	3081
26389	7590	05/18/2011		
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC			EXAMINER	
1420 FIFTH AVENUE			CHONG, YONG SOO	
SUITE 2800				
SEATTLE, WA 98101-2347			ART UNIT	PAPER NUMBER
			1627	
			NOTIFICATION DATE	DELIVERY MODE
			05/18/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@cojk.com

Office Action Summary	Application No. 10/555,076	Applicant(s) TAKAGI ET AL.	
	Examiner YONG CHONG	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41,43-48,55-57 and 59-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41,43-48,55-57 and 59-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to the Interview Summary filed on 5/2/2011.

Claim(s) 1-40, 42, 49-54, 58 have been cancelled. Claim(s) 41, 43-48, 55-57, 59-62 are pending and examined herein.

Per the Interview Summary filed on 5/2/2011, all rejections in the last Office Action filed on 10/29/2010 are hereby withdrawn. The following new rejections will now apply.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 44, 48, 57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 9-11, 14-19, 21 of copending Application No. 12/302,790 as evidenced by Applicant's

Art Unit: 1627

admission of the prior art. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 41, 43-48, 55-57, 59-62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,772,272 B2 as evidenced by Applicant's admission of the prior art.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the referenced claims recite administration of a HMG CoA reductase inhibitor (pravastatin) to a human suffering from diabetes and/or obesity.

Applicant's admission of the prior art teaches that in patients with circulatory diseases, diabetes, and obesity, blood adiponectin concentration decreases. Thus, disease states having decreased blood adiponectin concentrations, namely hypoadiponectinemia, are thought to be intimately related to lifestyle diseases (circulatory diseases, diabetes, and obesity) and are believed to be one of their basic causes. Thus, the treatment of hypoadiponectinemia is also useful in the treatment of the aforementioned lifestyle diseases caused by hypoadiponectinemia (background section on page 2).

Therefore, it is inherent that adiponectin production will be increased as hypoadiponectinemia is treated in the humans suffering from diabetes and/or obesity of the referenced claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 41, 43-48, 55-57, 59-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al. (US Patent 5,130,333) as evidenced by Applicant's admission of the prior art.

Pan et al. teach a method for treating Type II diabetes in a human by administering pravastatin (abstract, examples, and claims).

Applicant's admission of the prior art teaches that in patients with circulatory diseases, diabetes, and obesity, blood adiponectin concentration decreases. Thus, disease states having decreased blood adiponectin concentrations, namely hypoadiponectinemia, are thought to be intimately related to lifestyle diseases (circulatory diseases, diabetes, and obesity) and are believed to be one of their basic causes. Thus, the treatment of hypoadiponectinemia is also useful in the treatment of the aforementioned lifestyle diseases caused by hypoadiponectinemia (background section on page 2).

Therefore, it is inherent that adiponectin production will be increased as hypoadiponectinemia is treated in the Type II diabetic patients in Pan et al.

Claim(s) 41, 43-48, 55-57, 59-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Doebber et al. (US Patent 6,020,382) as evidenced by Applicant's admission of the prior art.

Doebber et al. teaches a method for treating diabetes and obesity (abstract). Compounds of formula I lower triglyceride and/or cholesterol levels and raise HDL plasma levels, therefore useful in combating medical conditions wherein such lowering is thought to be beneficial, which includes obesity and diabetes (col. 10, lines 56-65). Compounds of formula I can be combined with inhibitors of cholesterol synthesis, such as pravastatin, a HMG-CoA reductase inhibitor (col. 11, lines 4-6). Doebber et al. teaches a single oral dosage composition comprising a compound of formula I and the HMG-CoA reductase inhibitor, pravastatin (col. 12, lines 60-64 and col. 13, lines 28-32).

Applicant's admission of the prior art teaches that in patients with circulatory diseases, diabetes, and obesity, blood adiponectin concentration decreases. Thus, disease states having decreased blood adiponectin concentrations, namely hypoadiponectinemia, are thought to be intimately related to lifestyle diseases (circulatory diseases, diabetes, and obesity) and are believed to be one of their basic causes. Thus, the treatment of hypoadiponectinemia is also useful in the treatment of the aforementioned lifestyle diseases caused by hypoadiponectinemia (background section on page 2).

Therefore, it is inherent that adiponectin production will be increased as hypoadiponectinemia is treated in humans with diabetes or obesity in Doebber et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1627

YSC